

"Express Mail" Label No. EV 433 231 569 US

Date of Deposit: March, 31, 2004

PATENT

Attorney Docket No.: 15270J-004727US

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Mail Stop Patent Application

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

By:

*Rosemarie L. Colli*

In re application of:

SCHENK, Dale B.

Application No.: To be assigned

Filed: Herewith

For: PREVENTION AND TREATMENT  
OF AMYLOIDOGENIC DISEASE

Customer No.: 20350

Examiner: Unassigned

Technology Center/Art Unit: Unassigned

**Mail Stop Patent Application**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98**

Sir:

The references cited on the attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/201,430, filed November 30, 1998 (Attorney Docket No. 15270J-004720US), with the exception of reference numbers 407-435, copies of which are attached. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

The attached PTO/SB/08B form cites "'Grant Application; Raso, Immunology of Alzheimer's Disease', 1/1998,'" as cite no. 304. Cite no 304 was cited by the Examiner in Application No. 09/579,690. Application No. 09/579,690 is a commonly owned copending application directed to subject matter related to the instant application. Applicant believes "1/1998" is not the publication date as alleged by the Examiner, but refers to the grant funding cycle. Applicants' further believe the date of public accessibility, if any, is unknown. Applicant wishes to bring to the Examiner's attention that a copy of a grant application believed to have been submitted by Victor Raso for NIH Grant 1 R43 AGI 5746-01 on August 29, 1997 is cited in the attached PTO/SB/08B form as Cite 144. Cite no. 144 is a redacted version of cite no. 304. Applicant obtained cite no. 144 under the Freedom of Information Act (FOIA). It is believed that the grant proposal would not have been accessible under FOIA before April 2, 1998, but the exact date of public accessibility, if any, is not known to Applicant.

The Assignee of the instant application is a licensee of U.S. Patent No. 5,688,651, which is directed in part to subject matter related to the instant application. U.S. Patent No. 5,688,651 is now undergoing examination reissue as Application No. 09/441,140. U.S. Patent No. 5,688,651 and U.S. Application No. 09/441,140 are submitted herewith as Cite Nos. 16 and 283, respectively.

Applicant also cites commonly owned copending applications directed to related subject matter:

09/201,430 filed 11/30/98;  
09/497,553 filed 02/03/00;  
09/724,477 filed 11/28/00;  
09/723,927 filed 11/28/00;  
09/724,762 filed 11/28/00;  
09/724,102 filed 11/28/00;  
09/724,489 filed 11/28/00;

09/322,289 filed 05/28/99;  
09/723,713 filed 11/27/00;  
09/723,760 filed 11/27/00;  
09/724,319 filed 11/27/00;  
09/723,384 filed 11/27/00;  
09/724,495 filed 11/27/00;  
10/429,216 filed 05/30/03;  
09/580,015 filed 05/26/00;  
09/724,940 filed 11/28/00;  
09/724,961 filed 11/28/00;  
09/580,018 filed 05/26/00;  
09/724,552 filed 11/28/00;  
09/723,544 filed 11/28/00;  
09/724,273 filed 11/28/00;  
09/724,551 filed 11/28/00;  
09/724,288 filed 11/28/00;  
09/580,019 filed 05/26/00;  
09/723,765 filed 11/28/00;  
09/724,291 filed 11/28/00;  
09/204,838 filed 12/03/98;  
09/724,929 filed 11/28/00;  
09/585,817 filed 06/01/00;  
09/724,567 filed 11/28/00;  
09/724,575 filed 11/28/00;  
09/724,953 filed 11/28/00;  
09/724,570 filed 11/28/00;  
09/585,656 filed 06/01/00;  
09/723,766 filed 11/27/00;  
09/723,725 filed 11/27/00;  
09/579,690 filed 05/26/00;

09/979,701 filed 03/13/01 (U.S. National Stage of PCT/US00/14810 filed 05/26/00);  
09/979,952 filed 04/04/02 (U.S. National Stage of PCT/US00/15239 filed 06/01/00);  
and,  
09/980,568 filed 03/12/02 (U.S. National Stage of PCT/US00/15302 filed 06/01/00).

Applicant also cites the following copending applications directed to related  
subject matter but subject to different assignment:

10/010,942 filed 12/06/01;  
10/232,030 filed 08/30/02;  
10/388,389 filed 03/12/03;  
60/444,150 filed 02/01/03;  
10/388,214 filed 03/12/03; and,  
60/474,654 filed 05/30/03.

Applicant further cites the following commonly owned abandoned applications  
directed to related subject matter:

60/067,740 filed 12/02/97;  
60/080,970 filed 04/07/98;  
60/067,219 filed 12/03/97;  
60/079,697 filed 03/27/98;  
09/724,921 filed 11/28/00;  
60/137,010 filed 06/01/99;  
60/137,047 filed 06/01/99; and,  
60/136,655 filed 05/28/99.

Applicant also cites the following abandoned application directed to related  
subject matter but subject to different assignment:

60/251,892 filed 12/06/00; and,  
60/363,751 filed 03/12/02.

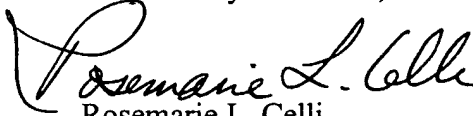
Applicant points out that the following applications are now commonly assigned but were previously subject to different assignment than the present application:

60/067,219 filed 12/03/97;  
60/079,697 filed 03/27/98;  
09/204,838 filed 12/03/98;  
09/724,921 filed 11/28/00; and,  
09/724,929 filed 11/28/00.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

  
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60172805 v1



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 25

**Complete if Known**

Application Number

Filing Date

First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

Herewith

Schenk

15270J-004727US

**U.S. PATENT DOCUMENTS**

| Examiner | Cite No. <sup>1</sup> | Document Number<br>Number Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|----------|-----------------------|---|--------------------------------|--|---|
|          | 415                   | 2003/0166558 A1   | 09-04-2003                     | Frangione et al.                                   |   |
|          | 431                   | 2003/0165496 A1   | 09-04-2003                     | Basi et al.  |   |
|          | 432                   | 6,562,341 B2  | 05-13-2003                     | Prusiner et al.                                    |   |
|          | 360                   | 2003/0073655 A1   | 04-17-2003                     | Chain  |   |
|          | 370                   | 2003/0068325 A1   | 04-10-2003                     | Wang   |   |
|          | 378                   | 2002/0197258 A1   | 12-26-2003                     | Ghanbari et al.                                    |   |
|          | 366                   | 2002/0187157 A1   | 12-12-2002                     | Jensen et al.                                      |   |
|          | 377                   | 2002/0168377 A1   | 11-14-2002                     | Schaetzel  |   |
|          | 340                   | 2002/0162129 A1   | 10-31-2002                     | Lannfelt   |   |
|          | 395                   | 2002/0160394 A1   | 10-31-2002                     | Wu   |   |
|          | 326                   | 2002/0136718 A1   | 09-26-2002                     | Raso   |   |
|          | 379                   | 2002/0132268 A1   | 09-19-2002                     | Chang et al.                                       |   |
|          | 365                   | 2002/0133001 A1   | 09-19-2002                     | Geffer et al.                                      |   |
|          | 325                   | 2001/0102261 A1   | 08-01-2002                     | Raso   |   |
|          | 362                   | 2002/0094335 A1   | 07-18-2002                     | Chalifour et al.                                   |   |
|          | 306                   | 6,417,178 B1  | 07-09-2002                     | Klunk et al.                                       |   |
|          | 376                   | 2002/0086847 A1   | 07-04-2002                     | Chain  |   |
|          | 405                   | 6,399,314 B1  | 06-04-2002                     | Krishnamurthy                                      |   |
|          | 342                   | 2002/0009445 A1   | 01-24-2002                     | Du et al.  |   |
|          | 267                   | 6,294,171 B2  | 09-25-2001                     | McMichael  |   |
|          | 416                   | 6,303,567 B1  | 10-16-2001                     | Findeis et al.                                     |   |
|          | 381                   | 2001/0021769 A1   | 09-13-2001                     | Prusiner   |   |
|          | 401                   | 6,284,533 B1  | 09-04-2001                     | Thomas   |   |
|          | 234                   | 6,284,221 B1  | 09-04-2001                     | Schenk, et al.                                     |   |
|          | 300                   | 2001/0018053 A1   | 08-30-2001                     | McMichael  |   |
|          | 230                   | 6,262,335 B1  | 07-17-2001                     | Hsiao et al.                                       |   |
|          | 345                   | 2002/0077288 A1   | 06-21-2001                     | Frangione  |   |
|          | 196                   | 6,150,091   | 11-21-2000                     | Pandolfo et al.                                    |   |
|          | 231                   | 6,114,133   | 09-05-2000                     | Seubert et al.                                     |   |
|          | 1                     | 6,057,367   | 05-02-2000                     | Stamler et al.                                     |   |
|          | 221                   | 5,989,566   | 11-23-1999                     | Cobb et al.  |   |
|          | 417                   | 5,985,242   | 11-16-1999                     | Findeis et al.                                     |   |

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<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2

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Application Number

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First Named Inventor

Art Unit

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Attorney Docket Number

Herewith

Schenk

15270J-004727US

|     |              |            |                   |
|-----|--------------|------------|-------------------|
| 2   | 5,958,883    | 09-28-1999 | Snow              |
| 3   | 5,955,317    | 09-21-1999 | Suzuki et al.     |
| 4   | 5,955,079    | 09-21-1999 | Mond et al.       |
| 346 | 5,935,927    | 08-10-1999 | Vitek et al.      |
| 5   | 5,877,399    | 03-02-1999 | Hsiao et al.      |
| 6   | 5,869,093    | 02-09-1999 | Weiner et al.     |
| 7   | 5,869,054    | 02-09-1999 | Weiner et al.     |
| 8   | 5,854,204    | 12-29-1998 | Findeis et al.    |
| 9   | 5,851,996    | 12-22-1998 | Kline             |
| 10  | 5,849,298    | 12-15-1998 | Weiner et al.     |
| 382 | 5,846,533    | 12-08-1998 | Prusiner          |
| 321 | 5,837,672    | 11-17-1998 | Schenk et al.     |
| 11  | 5,837,473    | 11-17-1998 | Maggio et al.     |
| 353 | 5,824,322    | 10-20-1998 | Balasubramanian   |
| 12  | 5,786,180    | 07-28-1998 | Konig et al.      |
| 207 | 5,780,587    | 07-14-1998 | Potter            |
| 357 | 5,776,468 B1 | 07-07-1998 | Hauser et al.     |
| 13  | 5,753,624    | 05-19-1998 | McMichael et al.  |
| 380 | 5,750,361    | 05-12-1998 | Prusiner et al.   |
| 14  | 5,750,349    | 05-12-1998 | Suzuki et al.     |
| 197 | 5,744,368    | 04-28-1998 | Goldgaber et al.  |
| 211 | 5,736,142    | 04-07-1998 | Sette et al.      |
| 15  | 5,733,547    | 03-31-1998 | Weiner et al.     |
| 373 | 5,721,130    | 02-24-1998 | Seubert et al.    |
| 16  | 5,688,651    | 11-18-1997 | Solomon           |
| 17  | 5,679,348    | 10-21-1997 | Nesburn et al.    |
| 18  | 5,645,820    | 07-08-1997 | Hafler et al.     |
| 19  | 5,641,474    | 06-24-1997 | Hafler et al.     |
| 20  | 5,641,473    | 06-24-1997 | Hafler et al.     |
| 356 | 5,622,701    | 04-22-1997 | Berg              |
| 21  | 5,612,486    | 03-18-1997 | McConlogue et al. |
| 22  | 5,605,811    | 02-25-1997 | Seubert et al.    |
| 320 | 5,593,846    | 01-14-1997 | Schenk et al.     |
| 23  | 5,585,100    | 12-17-1996 | Mond et al.       |
| 358 | 5,583,112 B2 | 12-10-1996 | Kensil et al.     |

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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| Application Number     |                 |
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| Art Unit               |                 |
| Examiner Name          |                 |
| Attorney Docket Number | 15270J-004727US |

|       |           |            |                     |
|-------|-----------|------------|---------------------|
| Sheet | 3         | of         | 25                  |
| 24    | 5,571,500 | 11-05-1996 | Haffer et al.       |
| 25    | 5,571,499 | 11-05-1996 | Haffer et al.       |
| 403   | 5,464,823 | 11-07-1995 | Lehrer et al.       |
| 175   | 5,441,870 | 08-15-1995 | Seubert, et al.     |
| 26    | 5,434,170 | 07-18-1995 | Andrulis, Jr.       |
| 27    | 5,387,742 | 02-07-1995 | Cordell             |
| 181   | 5,270,165 | 12-14-1993 | Van Nostrand et al. |
| 284   | 5,231,170 | 07-27-1993 | Averback            |
| 28    | 5,231,000 | 07-27-1993 | Majocha et al.      |
| 29    | 5,220,013 | 06-15-1993 | Ponte et al.        |
| 30    | 5,208,036 | 05-04-1993 | Eppstein et al.     |
| 31    | 5,192,753 | 03-09-1993 | McGeer et al.       |
| 32    | 5,187,153 | 02-16-1993 | Cordell et al.      |
| 33    | 5,057,540 | 10-15-1991 | Kensil et al.       |
| 198   | 5,004,697 | 04-20-1991 | Pardridge           |
| 402   | 4,713,366 | 12-15-1987 | Stevens             |
| 34    | 4,666,829 | 05-19-1987 | Glenner et al.      |

**U.S. PATENT DOCUMENTS**

| Examiner | Cite No. <sup>1</sup> | Document Number<br>Number Kind Code <sup>2</sup> (if known) | Filing Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|----------|-----------------------|---|---------------------------|--|---|
|          | 296                   | 60/254,465  | 12-08-2000                | Holtzman et al.                                    |   |
|          | 297                   | 60/254,498  | 12-08-2000                | Holtzman et al.                                    |   |
|          | 305                   | 09/724,842  | 11-28-2000                | Chalifour et al.                                   |   |
|          | 295                   | 60/184,601  | 02-24-2000                | Holtzman et al.                                    |   |
|          | 282                   | 60/169,687  | 12-08-1999                | Chain  |   |
|          | 242                   | 60/168,594  | 11-29-1999                | Chalifour et al.                                   |   |
|          | 283                   | 09/441,140  | 11-16-1999                | Solomon et al.                                     |   |
|          | 299                   | 60/186,295  | 03-01-2000                | Rasmussen et al.                                   |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Document   |                     |                                   | Publication<br>Date MM-DD-<br>YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|-----------------------|--------------------------|---------------------------|---------------------|-----------------------------------|------------------------------------|---|---|----------------|
|                       |                          | Country Code <sup>3</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |                                    |   |   |                |
|                       | 343                      | EP                        | 1 172 378           | A1                                | 01-16-2002                         |   |   |                |

|                       |  |                    |  |
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| Examiner<br>Signature |  | Date<br>Considered |  |
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| Examiner Name          |                 |
| Attorney Docket Number | 15270J-004727US |

|  |     |    |           |        |            |  |  |     |
|--|-----|----|-----------|--------|------------|--|--|-----|
|  | 35  | EP | 911 036   | A2     | 04-28-1999 |  |  |     |
|  | 36  | EP | 868 918   | A2     | 10-07-1998 |  |  |     |
|  | 37  | EP | 863 211   | A1     | 09-09-1998 |  |  |     |
|  | 38  | EP | 845 270   | A1     | 06-03-1998 |  |  |     |
|  | 39  | EP | 782 859   | A1     | 07-09-1997 |  |  |     |
|  | 40  | EP | 683 234   | A1     | 11-22-1995 |  |  |     |
|  | 41  | EP | 666 080   | A1     | 08-09-1995 |  |  |     |
|  | 42  | EP | 652 962   | B1     | 12-16-1998 |  |  |     |
|  | 43  | EP | 639 081   | B1     | 11-03-1999 |  |  |     |
|  | 44  | EP | 613 007   | A2     | 08-31-1994 |  |  |     |
|  | 45  | EP | 594 607   | B1     | 08-27-1997 |  |  |     |
|  | 46  | EP | 561 087   | B1     | 08-04-1999 |  |  |     |
|  | 47  | EP | 526 511   | B1     | 05-28-1997 |  |  |     |
|  | 48  | EP | 506 785   | B1     | 03-15-2000 |  |  |     |
|  | 49  | EP | 451 700   | A1     | 10-16-1991 |  |  |     |
|  | 50  | EP | 440 619   | B1     | 01-24-1996 |  |  |     |
|  | 51  | EP | 359 783   | B1     | 11-29-1995 |  |  |     |
|  | 52  | EP | 276 723   | B1     | 12-08-1993 |  |  | Yes |
|  | 187 | EP | 783 104   | A1     | 07-09-1997 |  |  |     |
|  | 433 | WO | 03/020212 | A2     | 03-13-2003 |  |  |     |
|  | 351 | WO | 02/34878  | A2     | 05-02-2002 |  |  |     |
|  | 352 | WO | 02/34777  | A1     | 05-02-2002 |  |  |     |
|  | 341 | WO | 02/03911  | A2     | 04-07-2001 |  |  |     |
|  | 344 | WO | 01/90182  | A2     | 11-29-2001 |  |  |     |
|  | 348 | WO | 01/77167  | A2     | 10-18-2001 |  |  |     |
|  | 294 | WO | 01/62801  | A2     | 08-30-2001 |  |  |     |
|  | 301 | WO | 01/62284  | A2     | 03-01-2000 |  |  |     |
|  | 298 | WO | 01/42306  | A2     | 06-14-2001 |  |  |     |
|  | 243 | WO | 01/39796  | A2     | 06-07-2001 |  |  |     |
|  | 199 | WO | 00/77178  | A1     | 12-21-2000 |  |  |     |
|  | 322 | WO | 00/72880  | A2, A3 | 12-07-2000 |  |  |     |
|  | 323 | WO | 00/72876  | A2, A3 | 12-07-2000 |  |  |     |
|  | 324 | WO | 00/72870  | A1     | 12-07-2000 |  |  |     |
|  | 240 | WO | 00/43039  | A1     | 07-27-2000 |  |  |     |
|  | 188 | WO | 00/43049  | A1     | 07-27-2000 |  |  |     |

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|     |    |          |    |            |  |  |  |
|-----|----|----------|----|------------|--|--|--|
| 53  | WO | 99/60024 | A1 | 11-25-1999 |  |  |  |
| 54  | WO | 99/60021 | A2 | 11-15-1999 |  |  |  |
| 55  | WO | 99/58564 | A1 | 11-18-1999 |  |  |  |
| 56  | WO | 99/06066 | A2 | 02-11-1999 |  |  |  |
| 57  | WO | 99/27949 | A1 | 06-10-1999 |  |  |  |
| 58  | WO | 99/27944 | A1 | 06-10-1999 |  |  |  |
| 59  | WO | 99/27911 | A1 | 06-10-1999 |  |  |  |
| 331 | WO | 99/06545 | A2 | 11-02-1999 |  |  |  |
| 203 | WO | 99/00150 | A2 | 01-07-1999 |  |  |  |
| 60  | WO | 98/44955 | A1 | 10-15-1998 |  |  |  |
| 61  | WO | 98/07850 | A2 | 02-26-1998 |  |  |  |
| 202 | WO | 97/21728 | A1 | 06-19-1997 |  |  |  |
| 62  | WO | 97/17613 | A1 | 05-15-1997 |  |  |  |
| 383 | WO | 97/10505 | A1 | 03-20-1997 |  |  |  |
| 63  | WO | 96/39176 | A1 | 12-12-1996 |  |  |  |
| 208 | WO | 96/28471 | A1 | 09-19-1996 |  |  |  |
| 64  | WO | 96/25435 | A1 | 08-22-1996 |  |  |  |
| 65  | WO | 96/18900 | A1 | 06-20-1996 |  |  |  |
| 66  | WO | 95/31996 | A1 | 11-30-1995 |  |  |  |
| 200 | WO | 95/12815 | A1 | 05-11-1995 |  |  |  |
| 67  | WO | 95/11994 | A1 | 05-04-1995 |  |  |  |
| 68  | WO | 95/11311 | A1 | 04-27-1995 |  |  |  |
| 227 | WO | 95/11008 | A2 | 04-27-1995 |  |  |  |
| 69  | WO | 95/05853 | A1 | 03-02-1995 |  |  |  |
| 70  | WO | 95/04151 | A2 | 02-09-1995 |  |  |  |
| 201 | WO | 94/28412 | A1 | 12-08-1994 |  |  |  |
| 71  | WO | 94/03615 | A1 | 02-17-1994 |  |  |  |
| 72  | WO | 94/01772 | A1 | 01-20-1994 |  |  |  |
| 73  | WO | 93/21950 | A1 | 11-11-1993 |  |  |  |
| 74  | WO | 93/16724 | A1 | 09-02-1993 |  |  |  |
| 75  | WO | 93/15760 | A1 | 08-19-1993 |  |  |  |
| 76  | WO | 93/14200 | A1 | 07-22-1993 |  |  |  |
| 205 | WO | 93/04194 | A1 | 03-04-1993 |  |  |  |
| 77  | WO | 93/02189 | A1 | 02-04-1993 |  |  |  |
| 78  | WO | 92/13069 | A1 | 08-06-1992 |  |  |  |

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|--|----|----|-----------|----|------------|--|--|--|
|  | 79 | WO | 92/06708  | A1 | 04-30-1992 |  |  |  |
|  | 80 | WO | 92/06187  | A1 | 04-16-1992 |  |  |  |
|  | 81 | WO | 91/19810  | A1 | 12-26-1991 |  |  |  |
|  | 82 | WO | 91/16819  | A1 | 11-14-1991 |  |  |  |
|  | 83 | WO | 91/12816  | A1 | 09-05-1991 |  |  |  |
|  | 84 | WO | 91/08760  | A1 | 06-27-1991 |  |  |  |
|  | 85 | WO | 90/12871  | A1 | 11-01-1990 |  |  |  |
|  | 86 | WO | 90/12870  | A1 | 11-01-1990 |  |  |  |
|  | 87 | WO | 89/01343  | A1 | 02-23-1989 |  |  |  |
|  | 88 | WO | 89/06242  | A1 | 07-13-1989 |  |  |  |
|  | 89 | WO | 89/06689  | A1 | 07-27-1989 |  |  |  |
|  | 90 | WO | 89/03687  | A1 | 05-05-1989 |  |  |  |
|  | 91 | WO | 88/10120  | A1 | 12-29-1988 |  |  |  |
|  | 92 | GB | 2 220 211 | A  | 01-04-1990 |  |  |  |
|  | 93 | GB | 2 335 192 | A  | 09-15-1999 |  |  |  |

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|------------------------|--------------------------|---|--------------------------|
|                        | 391                      | AGUZZI et al., "Prion research: the next frontiers," <u>Nature</u> , 389:795-798 (1997).  |                          |
|                        | 393                      | AKIYAMA et al., "Inflammation and Alzheimer's disease," <u>Neurobiology of Aging</u> , 21:383-421 (2000).   |                          |
|                        | 372                      | AKIYAMA et al., "Occurrence of the Diffuse Amyloid $\beta$ -Protein ( $A\beta$ ) Deposits With Numerous $A\beta$ -Containing Glial Cells in the Cerebral Cortex of Patients With Alzheimer's Disease," <u>Glia</u> , 25:324-331 (1999).                         |                          |
|                        | 94                       | ANDERSEN et al., "Do nonsteroidal anti-inflammatory drugs decrease the risk for Alzheimer's disease?," <u>Neurology</u> , 45:1441-1445 (1995).  | <input type="checkbox"/> |
|                        | 95                       | Associated Press, "Immune cells may promote Alzheimer's, a study finds," <u>The Boston Globe</u> (4/13/95).   | <input type="checkbox"/> |
|                        | 176                      | BARD et al., "Peripherally administered antibodies against amyloid $\beta$ -peptide enter the central nervous system and reduce pathology in a mouse model of Alzheimer disease," <u>Nature Medicine</u> , 6(8):916-919 (2000).                                 | <input type="checkbox"/> |
|                        | 228                      | BARROW et al., "Solution Conformations and aggregational Properties of Synthetic Amyloid Beta-Peptides of Alzheimer's Disease. Analysis of Circular Dichroism Spectra," <u>J. Mol.Biol.</u> , 225(4): 1075-1093 (1992).   |                          |
|                        | 96                       | BAUER et al., "Interleukin-6 and $\alpha$ -2-macroglobulin indicate an acute-phase state in Alzheimer's disease cortices," <u>FEBS Letters</u> , 285(1):111-114 (1991).   | <input type="checkbox"/> |
|                        | 239                      | BEASLEY, "Alzheimer's traced to proteins caused by aging," Reuters, April 20, 2001 7:56 PM ET.  |                          |
|                        | 404                      | BENJAMINI and LESKOWITZ, from <u>IMMUNOLOGY A Short Course</u> , Second Edition, Chapter 4, Antibody Structure, pages 49-65, 1991, published by Wiley-Liss, Inc., New York, New York.   |                          |
|                        | 204                      | BERCOVICI et al., "Chronic Intravenous Injections of Antigen Induce and Maintain Tolerance in T Cell Receptor-Transgenic Mice," <u>Eur. J. Immunol.</u> , 29:345-354 (1999).  |                          |
|                        | 212                      | BICKEL et al., "Site Protected, Cationized Monoclonal Antibody Against Beta Amyloid as a Potential Diagnostic Imaging Technique for Alzheimer's Diseases," <u>Soc. for Neuroscience Abstracts</u> , 18:764 (1992).  |                          |

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|  |       | First Named Inventor     | Schenk          |
|  |       | Art Unit                 |                 |
|  |       | Examiner Name            |                 |
| Sheet 8  | of 25 | Attorney Docket Number   | 15270J-004727US |

|     |   |                          |
|-----|---|--------------------------|
| 97  | BLASS, "Immunologic Treatment of Alzheimer's Disease," <u>New England J. Medicine</u> , 341(22):1694 (1999).  | <input type="checkbox"/> |
| 98  | BODMER et al., "Transforming Growth Factor-Beta Bound to Soluble Derivatives of the Beta Amyloid Precursor Protein of Alzheimer's Disease," <u>Biochem. Biophys. Res. Comm.</u> , 171(2):890-897 (1990).  | <input type="checkbox"/> |
| 99  | BORCHELT et al., "Accelerated Amyloid Deposition in the Brains of Transgenic Mice Coexpressing Mutant Presenilin 1 and Amyloid Precursor Proteins," <u>Neuron</u> , 19: 939-945 (1997).   | <input type="checkbox"/> |
| 418 | BORK, P., "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle," <u>Genome Research</u> , 10:398-400 (2000)  |                          |
| 419 | BORK et al., "Go hunting in sequence databases but watch out for the traps," <u>Trends in Genetics</u> , 12(10):425-427 (1996).   |                          |
| 100 | BORIS-LAWRIE et al., "Recent advances in retrovirus vector technology," <u>Cur. Opin. Genetic Develop.</u> , 3: 102-109 (1993).   | <input type="checkbox"/> |
| 420 | BRENNER, S. E., "Errors in genome annotation," <u>Trends in Genetics</u> , 15(4):132-133 (1999).  |                          |
| 101 | BRICE et al., "Absence of the amyloid precursor protein gene mutation (APP717 : Val->Ile) in 85 cases of early onset Alzheimer's disease," <u>J. Neurology, Neurosurg. Psychiatry</u> , 56:112-115 (1993).  | <input type="checkbox"/> |
| 327 | CAMERON, "Recent Advances in Transgenic Technology," <u>Molecular Biotechnology</u> , 7:253-265 (1997).   |                          |
| 285 | CAPUTO et al., "Therapeutic approaches targeted at the amyloid proteins in Alzheimer's disease," <u>Clin. Neuropharm.</u> , 15:414A-414B (1992).  |                          |
| 421 | CASTILLO et al., "Amylin / Islet Amyloid Polypeptide: Biochemistry, Physiology, Patho-Physiology," <u>Diabete &amp; Metabolisme (Paris)</u> , 21:3-25 (1995).   |                          |
| 224 | Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Thimerosal in Vaccines (Mercury in Plasma-Derived Products), web site contents found at : <a href="http://www.fda.gov/cber/vaccine/thimerosal.htm">http://www.fda.gov/cber/vaccine/thimerosal.htm</a> , last updated May 16, 2002. |                          |
| 102 | CHAO et al., "Transforming Growth Factor- $\beta$ Protects human Neurons Against $\beta$ -Amyloid-Induced Injury," <u>Soc. Neurosci. Abstracts</u> , 19:513-7 (1993).   | <input type="checkbox"/> |
| 266 | CHAPMAN, "Model behavior," <u>Nature</u> , 408:915-916 (2000).  |                          |
| 349 | CHECK, "Battle of the Mind," <u>Nature</u> , 422:370-372 (March 2003).  |                          |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
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|     |   |
|-----|---|
| 222 | Chemical Abstract database, Abstract of "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals," Chemical Abstract database. (Publication date unknown.)   |
| 332 | CHEN et al., "Neurodegenerative Alzheimer-like pathology in PDAPP 717V→F transgenic mice," <u>Progress in Brain Research</u> , Van Leeuwen et al. Eds, 117:327-337 (1998).  |
| 213 | CHEN et al., "An Antibody to $\beta$ Amyloid Precursor Protein Inhibits Cell-substratum Adhesion in Many Mammalian Cell Types," <u>Neuroscience Letters</u> , 125:223-226 (1991).   |
| 307 | CHEN et al., "A learning deficit related to age and beta-amyloid plaques in a mouse model of Alzheimer's disease," <u>Nature</u> , 408(6815):975-9 (2000).  |
| 302 | CHUNG et al., "Uptake, Degradation, and Release of Fibrillar and Soluble Forms of Alzheimer's Amyloid $\beta$ -Peptide by Microglial Cells," <u>J. Biol. Chem.</u> , 274(45):32301-32308 (1999).  |
| 291 | COLOMA et al., "Transport Across the Primate Blood-Brain Barrier of a Genetically Engineered Chimeric Monoclonal Antibody to the Human Insulin Receptor," <u>Pharm. Res.</u> , 17:266-274 (2000).   |
| 333 | CONWAY et al., "Acceleration of oligomerization, not fibrillization, is a shared property of both $\alpha$ -synuclein mutations linked to early-onset Parkinson's disease: Implications for pathogenesis and therapy," <u>PNAS</u> , 97(2):571-576 (2000)   |
| 286 | CORDELL, B., " $\beta$ -Amyloid formation as a potential therapeutic target for Alzheimer's disease," <u>Ann. Rev. Pharmacol. Toxicol.</u> , 34:69-89 (1994).   |
| 287 | COSTA et al., "Immunoassay for transthyretin variants associated with amyloid neuropathy," <u>Scand. J. Immunol.</u> , 38:177-182 (1993).   |
| 293 | DALY, et al., "Detection of the membrane-retained carboxy-terminal tail containing polypeptides of the amyloid precursor protein in tissue from Alzheimer's Disease brain," <u>Life Sci.</u> , 63:2121-2131 (1998).   |
| 412 | DAS et al., "Amyloid- $\beta$ Immunization Effectively Reduces Amyloid Deposition in FcR $\gamma$ Knock-Out-Mice," <u>J. Neuroscience</u> , 23(24):8532-8538 (2003).  |
| 214 | DEMATTOIS et al., "Peripheral Anti A $\beta$ Antibody Alters CNS And Plasma A $\beta$ Clearance and Decreases Brain A $\beta$ Burden in a Mouse Model of Alzheimer's Disease," <u>Proc. Natl. Acad. Sci. USA</u> , 10.1073/pnas.151261398 (2001).   |
| 220 | Dialog/Derwent, Abstract of WPI Acc No: 1997-054436/199706: Stable vaccine compsns. - comprise a macrocyclic lactone, a milbemycin, an avermectin, an antigen, a dispersing agent, an adjuvant, a water sol. organic solvent and saline or water, Derwent File 351: Derwent WPI database. (Publication date unknown.) |

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|     |  |  |
|-----|--|--|
| 390 | DIOMEDE et al., "Activation effects of a prion protein fragment [PrP-(106-126)] on human leucocytes," <u>Biochem. J.</u> , 320:563-570 (1996).   |  |
| 363 | DODART, "Immunotherapy for Alzheimer's disease: will vaccination work?" <u>Trends in Molecular Medicine</u> , 9(3):85-87 (2003).   |  |
| 422 | DOERKS et al., "Protein annotation: detective work for function prediction," <u>Trends in Genetics</u> , 14(6):248-250 (1998).   |  |
| 318 | DU et al., "Reduced levels of amyloid beta-peptide antibody in Alzheimer disease," <u>Neurology</u> , 57(5):801-5 (2001).  |  |
| 103 | DUFF et al., "Mouse model made," <u>Nature</u> , 373: 476-477 (1995).  |  |
| 288 | DUMERY et al., " $\beta$ -Amyloid protein aggregation: its implication in the physiopathology of Alzheimer's disease," <u>Pathol. Biol.</u> , 49:72-85 (2001).   |  |
| 407 | ECK et al., <i>Goodman and Gilman's The pharmacological basis of therapeutics</i> , Chapter 5, pages 77-101 (1996)   |  |
| 225 | Elan, "Elan and AHP Provide an Update on the Phase 2A Clinical Trial of AN-1792," Press Release. (1/18/2002).  |  |
| 226 | Elan, "Elan and Wyeth Provide Update on Status of Alzheimer's Collaboration," Press Release (3/1/2002)   |  |
| 104 | ELIZAN et al., "Antineurofilament antibodies in a postencephalitic and idiopathic Parkinson's disease," <u>J. Neurol. Sciences</u> , 59:341-347 (1983).  |  |
| 289 | ESIRI, "Is an effective immune intervention for Alzheimer's disease in prospect?", <u>Trends in Pharm. Sci.</u> , 22:2-3 (2001).   |  |
| 105 | FELSENSTEIN et al., "Processing of the $\beta$ -amyloid precursor protein carrying the familial, Dutch-type, and a novel recombinant C-terminal mutation," <u>Neuroscience Letters</u> , 152:185-189 (1993).     |  |
| 328 | FELSENSTEIN et al., "Transgenic Rat and In-Vitro Studies of B-Amyloid Precursor Protein Processing," <u>Alzheimer's and Parkinson's Diseases</u> , Hanin et al. Ed., pp 401-409, Plenum Press, New York, (1995). |  |
| 106 | FINCH et al., "Evolutionary Perspectives on Amyloid and Inflammatory Features of Alzheimer Disease," <u>Neurobiology of Aging</u> , 17(5):809-815 (1996).  |  |
| 107 | FISHER et al., "Expression of the amyloid precursor protein gene in mouse oocytes and embryos," <u>PNAS</u> , 88:1779-1782 (1991).   |  |

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|       |    |    |    | First Named Inventor   | Schenk          |
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|       |    |    |    | Attorney Docket Number | 15270J-004727US |

|     |   |  |
|-----|---|--|
| 108 | FLANDERS et al., "Altered expression of transforming growth factor- $\beta$ in Alzheimer's disease," <u>Neurology</u> , 45:1561-1569 (1995).  |  |
| 423 | FONSECA et al., "The Presence of Isoaspartic Acid in $\beta$ -Amyloid Plaques Indicates Plaque Age," <u>Experimental Neurology</u> , 157(2):277-288 (1999).   |  |
| 386 | FRAUTSCHY et al., "Effects of injected Alzheimer $\beta$ -amyloid cores in rat brain," <u>PNAS</u> , 88:8362-8366 (1991).   |  |
| 246 | FRENKEL et al., "Generation of auto-antibodies towards Alzheimer's disease vaccination," <u>Vaccine</u> , 19:2615-2619 (2001).  |  |
| 245 | FRENKEL et al., "High affinity binding of monoclonal antibodies to the sequential epitope EFRH of $\beta$ -amyloid peptide is essential for modulation of fibrillar aggregation," <u>J. of Neuroimmunology</u> , 95:136-142 (1999). |  |
| 247 | FRENKEL et al., "Immunization against Alzheimer's $\beta$ -amyloid plaques via EFRH phage administration," <u>PNAS USA</u> , 97:11455-11459 (2000).   |  |
| 248 | FRENKEL et al., "N-terminal EFRH sequence of Alzheimer's $\beta$ -amyloid peptide represents the epitope of its anti-aggregating antibodies," <u>J. of Neuroimmunology</u> , 88:85-90 (1998).                                       |  |
| 244 | FRENKEL, et al., "Modulation of Alzheimer's $\beta$ -amyloid neurotoxicity by site-directed single chain antibody," <u>J. of Neuroimmunology</u> , 106:23-31 (2000).  |  |
| 210 | FRIEDLAND et al., "Development of an anti-A $\beta$ monoclonal antibody for in vivo imaging of amyloid angiopathy in Alzheimer's disease," <u>Mol. Neurology</u> , 9:107-113 (1994).  |  |
| 249 | FRIEDLAND, et al., "Neuroimaging of Vessel Amyloid in Alzheimer's Disease," in <u>Cerebrovascular Pathology in Alzheimer's Disease</u> , eds. de la Torre and Hachinski, New York Academy of Sciences, New York, New York (1997).   |  |
| 364 | FURLAN et al., "Vaccination with amyloid- $\beta$ peptide induces autoimmune encephalomyelitis in C57/BL6 mice," <u>Brain</u> , 126:285-291 (2003).   |  |
| 109 | GAMES et al., "Alzheimer-type neuropathology in transgenic mice overexpressing V717F $\beta$ -amyloid precursor protein," <u>Nature</u> , 373(6514): 523-527 (1995).  |  |
| 215 | GAMES et al., "Prevention and Reduction of AD-type Pathology in PDAPP Mice Immunized with A $\beta$ <sub>1-42</sub> ," <u>Annals of the New York Academy of Science</u> 920:274-84 (2000).  |  |
| 110 | GANDY et al., "Amyloidogenesis in Alzheimer's disease: some possible therapeutic opportunities," <u>TIPS</u> , 13:108-113 (1992).   |  |

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|-----|---|
| 251 | GARDELLA et al., "Intact Alzheimer amyloid precursor protein (APP) is present in platelet membranes and is encoded by platelet mRNA," <u>Biochem. Biophys. Res. Comm.</u> , 173:1292-1298 (1990).   |
| 111 | GASKIN et al., "Human antibodies reactive with beta-amyloid protein in Alzheimer's disease," <u>J. Exp. Med.</u> , 177:1181-1186 (1993).  |
| 252 | GEDDES, "N-terminus truncated $\beta$ -amyloid peptides and C-terminus truncated secreted forms of amyloid precursor protein: distinct roles in the pathogenesis of Alzheimer's disease," <u>Neurobiology of Aging</u> , 20:75-79 (1999). |
| 253 | GIULIAN, et al., "The HHQK Domain of b-Amyloid Provides a Structural Basis for the Immunopathology of Alzheimer's Disease," <u>Journal of Biological Chem.</u> , 273:29719-29726 (1998).  |
| 112 | GLENN et al., "Skin immunization made possible by cholera toxin," <u>Nature</u> , 391: 851 (1998).  |
| 114 | GLENNER et al., "Alzheimer's Disease and Downs Syndrome: Sharing of A Unique Cerebrovascular Amyloid Fibril Protein," <u>Biochemical and Biophysical Research Communications</u> , 122(3): 1131-1135 (1984).                              |
| 113 | GLENNER et al., "Alzheimer's Disease: Initial Report of the Purification and Characterization of a Novel Cerebrovascular Amyloid Protein," <u>Biochemical and Biophysical Research Communications</u> , 120(3): 885-890 (1994).           |
| 115 | GOATE et al., "Segregation of a missense mutation in the amyloid precursor protein gene with familial Alzheimer's disease," <u>Nature</u> , 349:704-706 (1991).   |
| 388 | GOLDFARB et al., "The Transmissible Spongiform Encephalopathies," <u>Ann. Rev. Med.</u> , 46:57-65 (1995).  |
| 424 | GOLDSBY et al., "Vaccines," Chapter 18 from <u>Immunology, 4th Edition</u> , W.H. Freeman and Company, New York, pages 449-465.   |
| 397 | GOLDSTEINS et al., "Goldsteins et al., Exposure of cryptic epitopes on transthyretin only in amypoid and in amyloidogenic mutants," <u>PNAS</u> , 96:3108-3113 (1999).  |
| 303 | GONZALES-FERNANDEZ et al., "Low antigen dose favors selection of somatic mutants with hallmarks of antibody affinity maturation," <u>Immunology</u> , 93:149-153 (1998).  |
| 237 | GORTNER, <u>Outlines of Biochemistry</u> , pp. 322-323, John Wiley & Sons, Inc., New York (1949).   |
| 116 | GOZES et al., "Neuroprotective strategy for Alzheimer disease: Intranasal administration of a fatty neuropeptide," <u>PNAS USA</u> , 93:427-432 (1996).   |

|                    |  |                 |  |
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|-----|---|
| 190 | GRAVINA et al., "Amyloid $\beta$ Protein ( $A\beta$ ) in Alzheimer's Disease," <u>J. Biol. Chem.</u> , 270(13):7013-7016 (1995).  |
| 254 | GRUBECK-LOEBENSTEIN, et al., "Immunization with $\beta$ -amyloid: could T-cell activation have a harmful effect?", <u>TINS</u> , 23:114 (2000).   |
| 117 | GUPTA et al., "Differences in the immunogenicity of native and formalized cross reacting material (CRM197) of diphtheria toxin in mice and guinea pigs and their implications on the development and control of diphtheria vaccine based on CRMs," <u>Vaccine</u> , 15(12/13): 1341-1343 (1997).      |
| 241 | HAASS et al. "Amyloid beta-peptide is produced by cultured cells during normal metabolism," <u>Nature</u> , 359(6393):322-5 (1992).   |
| 118 | HAGA et al., "Synthetic Alzheimer amyloid $\beta$ /A4 peptides enhance production of complement C3 component by cultured microglial cells," <u>Brain Research</u> , 601:88-94 (1993).   |
| 182 | HANAN and SOLOMON, "Inhibitory effect of monoclonal antibodies on Alzheimer's $\beta$ -amyloid peptide aggregation," <u>Int. J. Exp. Clin. Invest.</u> , 3:130-133 (1996).  |
| 119 | HANES et al., "New advances in microsphere-based single-dose vaccines," <u>Advanced Drug Delivery Reviews</u> , 28: 97-119 (1997).  |
| 120 | HARDY, "Amyloid, the presenilins and Alzheimer's disease," <u>TINS</u> , 20(4): 154-159 (1997).   |
| 121 | HARDY, John, "New Insights into the Genetics of Alzheimer's Disease," <u>Annals of Med.</u> , 28:255-258 (1996).  |
| 255 | HARIGAYA, et al., "Modified amyloid $\beta$ protein ending at 42 or 40 with different solubility accumulates in the brain of Alzheimer's disease," <u>Biochem. Biophys. Res. Comm.</u> , 211:1015-1022 (1995).  |
| 193 | HARRINGTON et al., "Characterization of an epitope specific to the neuron-specific isoform of human enolase recognized by a monoclonal antibody raised against a synthetic peptide corresponding to the C-terminus of $\beta$ / A4-protein," <u>Biochimica Biophysica Acta</u> , 1158:120-128 (1993). |
| 229 | HAZAMA, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by Using a Recombinant Glycoprotein D Fused With Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2", <u>Immunology</u> , Vol. 78: 643-649 (1993).                |
| 177 | HELMUTH, "Further Progress on a $\beta$ -Amyloid Vaccine," <u>Science</u> , 289:375 (2000).   |
| 236 | HILBICH et al., "Human and rodent sequence analogs of Alzheimer's amyloid $\beta$ A4 share similar properties and can be solubilized in buffers of pH 7.4," <u>Eur. J. Biochem.</u> , 201:61-69 (1991).   |

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|     |   |
|-----|---|
| 413 | HOLTZMAN et al., "A $\beta$ immunization and anti-A $\beta$ antibodies: potential therapies for the prevention and treatment of Alzheimer's disease," <u>Advanced Drug Delivery Reviews</u> , 54:1603-1613 (2002).                  |
| 122 | HSIAO et al., "Correlative Memory Deficits, A $\beta$ Elevation, and Amyloid Plaques in Transgenic Mice," <u>Science</u> , 274: 99-102 (1996).  |
| 123 | HUBERMAN et al., "Correlation of cytokine secretion by mononuclear cells of Alzheimer's patients and their disease stage," <u>J. Neuroimmunology</u> , 52:147-152 (1994).   |
| 174 | Human Immunology & Cancer Program brochure, from The University of Tennessee Medical Center/ Graduate School of Medicine, Knoxville, Tennessee (publication date unknown).  |
| 124 | HYMAN et al., "Molecular Epidemiology of Alzheimer's Disease," <u>N. E. J. Medicine</u> , 333(19):1283-1284 (1995).   |
| 256 | IKEDA, et al., "Immunogold labeling of cerebrovascular and neuritic plaque amyloid fibrils in Alzheimer's disease with an anti- $\beta$ protein monoclonal antibody," <u>Lab. Invest.</u> , 57:446-449 (1987).                      |
| 125 | ITAGAKI et al., "Relationship of microglia and astrocytes to amyloid deposits of Alzheimer's disease," <u>J. Neuroimmunology</u> , 24:173-182 (1989).   |
| 192 | IWATSUBO et al., "Visualization of A $\beta$ 42(43) and A $\beta$ 40 in Senile Plaques with End-Specific A $\beta$ Monoclonals: Evidence That an Initially Deposited Species Is A $\beta$ 42(43)," <u>Neuron</u> , 13:45-53 (1994). |
| 374 | JAKES et al., "Characterisation of an Antibody Relevant to the Neuropathology of Alzheimer Disease," <u>Alzheimer Disease and Associated Disorders</u> , 9(1):47-51, Raven Press, Ltd., New York (1995).                            |
| 126 | JANSEN et al., "Immunotoxins: Hybrid Molecules Combining High Specificity and Potent Cytotoxicity," <u>Immun. Rev.</u> , 62: 185-216 (1982).  |
| 308 | JANUS et al., "A beta peptide immunization reduces behavioural impairment and plaques in a model of Alzheimer's disease," <u>Nature</u> , 408(6815):979-82 (2000).  |
| 257 | JEN, et al., "Preparation and purification of antisera against different regions or isoforms of b-amyloid precursor protein," <u>Brain Research Protocols</u> , 2:23-30 (1997).   |
| 216 | JOACHIM et al., "Antibodies to Non-beta Regions of the Beta-amyloid Precursor Protein Detect a Subset of Senile Plaques," <u>Am. J. of Pathology</u> , 138:373-384 (1991).  |
| 334 | JOBLING and HOLMES, "Analysis of structure and function of the B subunit of cholera toxin by the use of site-directed mutagenesis," <u>Molecular Microbiology</u> , 5(7):1755-1767 (1991).  |
| 371 | JOHNSTONE et al., Nuclear and Cytoplasmic Localization of the $\beta$ -Amyloid Peptide (1-43) in Transfected 293 Cells," <u>Biochemical and Biophysical Research Communications</u> , 220:710-718 (1996).                           |

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| Examiner Name          |                 |
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|     |  |  |
|-----|--|--|
| 347 | JORBECK et al., "Artificial <i>Salmonella</i> Vaccines: <i>Salmonella typhimurium</i> O-antigen-Specific Oligosaccharide-Protein Conjugates Elicit Opsonizing Antibodies that Enhance Phagocytosis," <u>Infection and Immunity</u> , May:497-502 (1981). |  |
| 127 | KALARIA, R. N., "Serum amyloid P and related molecules associated with the acute-phase response in Alzheimer's disease," <u>Res. Immunology</u> , 143:637-641 (1992).  |  |
| 183 | KATZAV-GOZANSKY et al., "Effect of monoclonal antibodies in preventing carboxypeptidase A aggregation," <u>Biotechnol. Appl. Biochem.</u> , 23:227-230 (1996).   |  |
| 128 | KAWABATA et al., "Amyloid plaques, neurofibrillary tangles and neuronal loss in brains of transgenic mice overexpressing a C-terminal fragment of human amyloid precursor protein," <u>Nature</u> , 354:476-478 (1991).                                  |  |
| 434 | KELLY, J. W., "Alternative conformations of amyloidogenic proteins govern their behavior," <u>Current Opinion in Structural Biology</u> , 6:11-17 (1996).  |  |
| 258 | KIDA, et al., "Early amyloid- $\beta$ deposits show different immunoreactivity to the amino- and carboxy-terminal regions of b-peptide in Alzheimer's disease and Down's syndrome brain," <u>Neuroscience Letters</u> , 193:105-108 (1995).              |  |
| 195 | KONIG et al., "Development and Characterization of a Monoclonal Antibody 369.2B Specific for the Carboxyl-Terminus of the $\beta$ A4 Peptide," <u>Annals of NY Acad. Sci.</u> , 777:344-355 (1996).  |  |
| 389 | KOVÁCS et al., "Mutations of the Prion Protein Gene Phenotypic Spectrum," <u>J. Neurol.</u> , 249:1567-1582 (2002).  |  |
| 129 | LAMPERT-ETCHELLS et al., "Regional Localization of Cells Containing Complement C1q and C4 mRNAs in the Frontal Cortex During Alzheimer's Disease," <u>Neurodegeneration</u> , 2:111-121 (1993).  |  |
| 130 | LANGER, "New Methods of Drug Delivery," <u>Science</u> , 249: 1527-1532 (1990).  |  |
| 131 | LANNFELT et al., "Alzheimer's disease: molecular genetics and transgenic animal models," <u>Behavioural Brain Res.</u> , 57:207-213 (1993).  |  |
| 259 | LANSBURY, PETER T., "Inhibition of amyloid formation: a strategy to delay the onset of Alzheimer's disease," <u>Curr. Ops. in Chemical Biology</u> , 1:260-267 (1997).   |  |
| 132 | LEMERE et al., "Mucosal Administration of A $\beta$ Peptide Decreases Cerebral Amyloid Burden In Pd-App Transgenic Mice," <u>Society for Neuroscience Abstracts</u> , vol. 25, part I, Abstract 519.6, 29th Annual Meeting, (October 23-28, 1999).       |  |
| 260 | LEMERE, et al., "Nasal A $\beta$ treatment induces anti-A $\beta$ antibody production and decreases cerebral amyloid burden in PD-APP mice," <u>Annals of the NY Acad. Sci.</u> , 920:328-331 (2000).  |  |

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|   |                        | Examiner Name            |          |
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|     |   |  |
|-----|---|--|
| 184 | LI and SOLOMON, "Thermal Stabilization of Carboxypeptidase A as a Function of PH and Ionic Milieu," <u>Biochem. Mol. Biol. Int.</u> , 43(3):601-611 (1997).   |  |
| 133 | LIVINGSTON et al., "The Hepatitis B Virus-Specific CTL Responses Induced in Humans by Lipopeptide Vaccination Are Comparable to Those Elicited by Acute Viral Infection," <u>J. Immunol.</u> , 159: 1383-1392 (1997).                 |  |
| 134 | LOPEZ et al., "Serum auto-antibodies in Alzheimer's disease," <u>Acta. Neurol. Scand.</u> , 84:441-444 (1991).  |  |
| 218 | MAJOCHA et al., "Development of a Monoclonal Antibody Specific for $\beta$ /A4 Amyloid in Alzheimer's Disease Brain for Application to In Vitro Imaging of Amyloid Angiopathy," <u>The J. of Nuclear Med.</u> 33:2184-2189 (1992).    |  |
| 261 | MAK, et al., "Polyclonals to b-amyloid (1-42) identify most plaque and vascular deposits in Alzheimer cortex, but not striatum," <u>Brain Research</u> , 667:138-142 (1994).  |  |
| 263 | MANN, et al., "Amyloid $\beta$ protein ( $A\beta$ ) deposition in chromosome 14-linked Alzheimer's disease: Predominance of $A\beta_{42(43)}$ ," <u>Annals of Neurology</u> , 40:149-156 (1996).                                      |  |
| 262 | MANN, et al., "The extent of amyloid deposition in brain in patients with Down's syndrome does not depend upon the apolipoprotein E genotype," <u>Neuroscience Letters</u> , 196:105-108 (1995).                                      |  |
| 408 | MARSHALL, E., "Gene Therapy's Growing Pains," <u>Science</u> , 269:1050-1055 (1995).  |  |
| 335 | MASLIAH et al., " $\beta$ -Amyloid peptides enhance $\alpha$ -synuclein accumulation and neuronal deficits in a transgenic mouse model linking Alzheimer's disease and Parkinson's disease," <u>PNAS</u> , 98(21):12245-12250 (2001). |  |
| 217 | MASTERS et al., "Amyloid Plaque core protein in Alzheimer Disease and Down Syndrome," <u>Proc. Natl. Acad. Sci. USA</u> , 82:4245-4249 (1985).  |  |
| 309 | MATTSON, Cellular actions of beta-amyloid precursor protein and its soluble and fibrillogenic derivatives. <u>Physiol Rev.</u> 77(4):1081-132 (1997).   |  |
| 135 | MCGEE et al., "The encapsulation of a model protein in poly (D, L lactide-co-glycolide) microparticles of various sizes: an evaluation of process reproducibility," <u>J. Micro. Encap.</u> , 14(2): 197-210 (1997).                  |  |
| 264 | MCGEER, et al., "Immunohistochemical localization of beta-amyloid precursor protein sequences in Alzheimer and normal brain tissue by light and electron microscopy," <u>J. of Neuroscience Res.</u> , 31:428-442 (1992).             |  |
| 238 | MCNEAL et al., "Stimulation of local immunity and protection in mice by intramuscular immunization with triple- or double-layered rotavirus particles and QS-21," <u>Virology</u> , 243:158-166 (1998).                               |  |

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|     |   |  |
|-----|---|--|
| 136 | MEDA et al., "Activation of microglial cells by $\beta$ -amyloid protein and interferon- $\gamma$ ," <u>Nature</u> , 374:647-650 (1995).  |  |
| 265 | MENA, et al., "Monitoring pathological assembly of tau and $\beta$ -amyloid proteins in Alzheimer's disease," <u>Acta Neuropathol.</u> , 89:50-56 (1995).   |  |
| 310 | MERLUZZI, et al., "Humanized antibodies as potential drugs for therapeutic use," <u>Adv Clin Path.</u> , 4(2):77-85 (2000).   |  |
| 137 | MILLER et al., "Antigen-driven Bystander Suppression after Oral Administration of Antigens," <u>J. Exp. Med.</u> , 174:791-798 (1991).  |  |
| 367 | MONSONEGO et al., "Immune hyporesponsiveness to amyloid $\beta$ -peptide in amyloid precursor protein transgenic mice: Implications for the pathogenesis and treatment of Alzheimer's disease," <u>PNAS</u> , 98(18):10273-10278 (2001).  |  |
| 311 | MORGAN, et al., "A beta peptide vaccination prevents memory loss in an animal model of Alzheimer's disease," <u>Nature</u> , 408(6815):982-5 (2000).  |  |
| 206 | MORI et al., "Mass Spectrometry of Purified Amyloid $\beta$ Protein in Alzheimer's Disease," <u>J. Biol. Chem.</u> , 267(24):17082-17088 (1992).  |  |
| 233 | MORRIS, et al., "The Consortium to Establish a registry for Alzheimer's Disease (CERAD)," <u>Neurology</u> , 39:1159-65 (1989).   |  |
| 359 | MUNCH et al., "Potential neurotoxic inflammatory response to A $\beta$ vaccination in humans," (2002) <u>J. Neural Transm.</u> , 109:1081-1087.   |  |
| 355 | MUNSON ed., "Principals of Pharmacology: Basic Concepts & Clinical Applications," (1995), 47-48, Chapman & Hall, New York, New York.  |  |
| 191 | MURPHY et al., "Development of a Monoclonal Antibody Specific for the COOH-Terminal of $\beta$ -Amyloid 1-42 and Its Immunohistochemical Reactivity in Alzheimer's Disease and Related Disorders," <u>Am. J. Pathology</u> , 144(5):1082-1088 (1994).   |  |
| 354 | MUTSCHLER et al., "Drug Actions: Basic Principles and Therapeutic Aspects," (1995) 7, 11-12, <u>medpharm</u> Scientific Publishers, Stuttgart, Germany.   |  |
| 250 | NAKAMURA et al., "Histopathological studies on senile plaques and cerebral amyloid angiopathy in aged cynomolgus monkeys," <u>Exp. Anim.</u> , 43:711-718 (1995).   |  |
| 268 | NAKAMURA, et al., "Carboxyl end-specific monoclonal antibodies to amyloid $\beta$ protein (A $\beta$ ) subtypes (A $\beta$ 40 and A $\beta$ 42(43) differentiate Ab in senile plaques and amyloid angiopathy in brains of aged cynomolgus monkeys," <u>Neuroscience Letters</u> , 201:151-154 (1995). |  |

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| Sheet 18 of 25  | Attorney Docket Number | 15270J-004727US          |          |

|     |   |  |
|-----|---|--|
| 281 | NAKAYAMA et al., "Histopathological studies of senile plaques and cerebral amyloidosis in cynomolgus monkeys," <u>J. of Med. Primatology</u> , 27:244-252 (1998).   |  |
| 138 | NATHANSON et al., "Bovine Spongiform Encephalopathy (BSE): Causes and Consequences of a Common Source Epidemic," <u>Am. J. Epidemiol.</u> , 145(11): 959-969 (June 1, 1997).  |  |
| 139 | New York Times National, "Anti-Inflammatory Drugs May Impede Alzheimer's," (2/20/94).   |  |
| 235 | NEWCOMBE and COHEN, "Solubility characteristics of isolated amyloid fibrils," <u>Biochim. Biophys. Acta</u> , 104:480-486 (1965).   |  |
| 425 | NGO et al., "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox," pages 492-495 from Chapter 14 of <i>The Protein Folding Problem and Tertiary Structure Prediction</i> , Merz et al., eds., Birkhauser Boston (1994). |  |
| 350 | NICOLL et al., "Neuropathology of human Alzheimer's disease after immunization with amyloid- $\beta$ peptide: a case report," <u>Nature Medicine</u> , 9(4):448-452 (April 2003).   |  |
| 329 | NIEMANN, "Transgenic farm animals get off the ground," <u>Transgenic Research</u> 7:73-75 (1998).   |  |
| 409 | ORKIN et al., <i>Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy</i> , December 7, 1995  |  |
| 398 | PALHA et al., "Antibody recognition of amyloidogenic transthyretin variants in serum of patients with familial amyloidotic polyneuropathy," <u>J. Mol. Med.</u> , 7:703-707 (2001).   |  |
| 406 | PAN et al., "Antibodies to $\beta$ -Amyloid Decrease the Blood-to-Brain Transfer of $\beta$ -Amyloid Peptide," <u>Exp. Biol. Med.</u> , 227(8):609-615 (2002).  |  |
| 280 | PARDRIDGE et al., "Chimeric peptides as a vehicle for peptide pharmaceutical delivery through the blood-brain barrier," <u>Biochem. Biophys. Res. Comm.</u> , 146:307-313 (1987).   |  |
| 140 | PARESCIE et al., "Microglial cells influence aggregates of the Alzheimer's disease amyloid beta-protein via a scavenger receptor," <u>Neuron</u> , 17:553-565 (September 1996).   |  |
| 141 | PAUL et al., "Transdermal immunization with large proteins by means of ultradeformable drug carriers," <u>Eur. J. Immunol.</u> , 25: 3521-3524 (1995).  |  |
| 336 | PERUTZ et al., "Amyloid fibers are water-filled nanotubes," <u>PNAS</u> , 99(8):5591-5595 (2002).   |  |
| 232 | PETERSON, et al., "Recombinant Antibodies: Alternative Strategies for Developing and Manipulating Murine-Derived Monoclonal Antibodies," <u>Laboratory Animal Science</u> , 46(1):8-14 (1996).  |  |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
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|--------------------|--|-----------------|--|

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| Sheet 19 of 25  | Attorney Docket Number | 15270J-004727US          |          |

|                    |  |                 |
|--------------------|--|-----------------|
| 269                | PHILIPPE, et al. "Generation of a monoclonal antibody to the carboxy-terminal domain of tau by immunization with the amino-terminal domain of the amyloid precursor protein," <u>J. of Neuroscience Res.</u> , 46:709-719 (1996).                                |                 |
| 142                | PRIEELS et al., "Synergistic adjuvants for vaccines," <u>Chemical Abstracts</u> , 120(8): pg. 652, column 1, abstract 86406t (1994).   |                 |
| 394                | PRUSINER et al., "Ablation of the prion protein (PrP) gene in mice prevents scrapie and facilitates production of anti-PrP antibodies," <u>PNAS</u> , 90:10608-10612 (1993).   |                 |
| 143                | QUON et al., "Formation of $\beta$ -Amyloid protein deposits in brains of transgenic mice," <u>Nature</u> , 352:239-241 (1991).  |                 |
| 145                | RASO, "Immunotherapy of Alzheimer's Disease," <u>Immunotherapy Weekly</u> , Abstract (April 2, 1998).  |                 |
| 304                | RASO, V.A., Grant application # 1 R43 AGI 5746-01 (non-redacted version), "Immunotherapy of Alzheimer's Disease" (publication date unknown).   |                 |
| 144                | RASO, V.A., Grant application # 1 R43 AGI 5746-01 (redacted version), "Immunotherapy of Alzheimer's Disease" (publication date unknown).   |                 |
| 146                | ROGERS et al., "Complement activation by $\beta$ -amyloid in Alzheimer Disease," <u>PNAS</u> , 89:1-5 (1992).  |                 |
| 147                | ROSSOR et al., "Alzheimer's Disease Families with Amyloid Precursor Protein Mutations," <u>Annals of New York Academy of Sciences</u> , 695:198-202 (1993).  |                 |
| 209                | RUDINGER, "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence," in <u>Peptide Hormones</u> , J.A. Parson, ed. University Park Press, Baltimore, pp 1-7 (1976).   |                 |
| 189                | SAIDO et al., "Spatial Resolution of Fodrin Proteolysis in Postischemic Brain," <u>J. Biol. Chem.</u> , 268(33):25239-25243 (1993).  |                 |
| 194                | SAIDO et al., "Spatial Resolution of the Primary $\beta$ -Amyloidogenic Process Induced in Postischemic Hippocampus," <u>J. Biol. Chem.</u> , 269(21):15253-15257 (1994).  |                 |
| 279                | SAITO et al., "Vector-mediated delivery of $^{125}$ I-labeled $\beta$ -amyloid peptide Ab $^{1-40}$ through the blood-brain barrier and binding to Alzheimer disease amyloid of the A $\beta^{1-40}$ vector complex," <u>PNAS USA</u> , 92:10227-10231 (1995).** |                 |
| 278                | SAITOH, N. et al., "Immunological analysis of Alzheimer's disease using anti- $\beta$ -protein monoclonal antibodies," <u>Sapporo Med. J.</u> , 60:309-320 (1991).   |                 |
| 277                | SASAKI et al., "Human choroid plexus is an uniquely involved area of the brain in amyloidosis: a histochemical, immunohistochemical and ultrastructural study," <u>Brain Res.</u> , 755:193-201 (1997).  |                 |
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|     |   |  |
|-----|---|--|
| 148 | SCHENK et al., "Immunization with amyloid- $\beta$ attenuates Alzheimer-disease-like pathology in the PDAPP mouse," <u>Nature</u> , 400:173-177 (1999).               |  |
| 178 | SCHENK et al., "Therapeutic Approaches Related to Amyloid- $\beta$ Peptide and Alzheimer's Disease," <u>J. Med. Chem.</u> , 38(21):4141-4154 (1995).                  |  |
| 312 | SCHENK et al., "Immunotherapy with beta-amyloid for Alzheimer's disease: a new frontier," <u>DNA Cell Biol.</u> , 20(11):679-81 (2001).                               |  |
| 270 | SCHENK et al., " $\beta$ -peptide immunization," <u>Arch. Neurol.</u> , 57:934-936 (2000).  |  |
| 414 | SCHENK, D., "Amyloid- $\beta$ immunotherapy for Alzheimer's disease: the end of the beginning," <u>Nature Reviews</u> , 3:824-828 (2002).                             |  |
| 150 | SELKOE, "Alzheimer's Disease: A Central Role for Amyloid," <u>J. Neuropathol. Exp. Neurol.</u> , 53(5): 438-447 (1994).   |  |
| 151 | SELKOE, "Physiological production of the $\beta$ -amyloid protein and the mechanism of Alzheimer's disease," <u>Trends in Neurosciences</u> , 16(10): 403-409 (1993). |  |
| 149 | SELKOE, D.J., "Imaging Alzheimer's Amyloid," <u>Nat. Biotech.</u> , 18:823-824 (2000).  |  |
| 155 | SELKOE, Dennis J., "Alzheimer's Disease: Genotypes, Phenotype, and Treatments," <u>Science</u> , 275:630-631 (1997).  |  |
| 152 | SELKOE, Dennis J., "Amyloid Protein and Alzheimer's Disease.....," <u>Scientific American</u> , pgs. 68-78 (November, 1991).  |  |
| 153 | SELKOE, Dennis J., "In the Beginning....," <u>Nature</u> , 354:432-433 (1991).  |  |
| 154 | SELKOE, Dennis J., "The Molecular pathology of Alzheimer's Disease," <u>Neuron</u> , 6:487-498 (1991).  |  |
| 313 | SELKOE, "The cell biology of beta-amyloid precursor protein and presenilin in Alzheimer's disease," <u>Trends Cell Biol.</u> , 8(11):447-53 (1998).                   |  |
| 156 | SEUBERT et al., "Isolation and quantification of soluble Alzheimer's $\beta$ -peptide from biological fluids," <u>Nature</u> , 359: 325-327 (1992).                   |  |
| 157 | SHIOSAKA, S., "Attempts to make models for Alzheimer's disease," <u>Neuroscience Res.</u> , 13:237-255 (1992).  |  |
| 330 | SIGMUND, "Viewpoint: Are Studies in Genetically Altered Mice Out of Control," <u>Arterioscler Thromb Vasc Biol.</u> , 20:1425-1429 (2000).                            |  |

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|     |  |  |
|-----|--|--|
| 396 | SIGURDSSON et al., "Anti-priori antibodies for prophylaxis following prion exposure in mice," <u>Neurosciences Letters</u> , 336:185-187 (2003).   |  |
| 384 | SIGURDSSON et al., "Immunization Delays the Onset of Prion Disease in Mice," <u>American Journal of Pathology</u> , 161:13-17 (2002).  |  |
| 314 | SIGURDSSON, et al., "In vivo reversal of amyloid-beta lesions in rat brain," <u>J Neuropathol Exp Neurol.</u> , 59(1):11-17 (2000).  |  |
| 400 | SIGURDSSON et al., "A safer vaccine for Alzheimer's disease?," <u>Neurobiology of Aging</u> , 23:1001-1008 (2002).   |  |
| 426 | SINGH, K. S., "Neuroautoimmunity: Pathogenic Implications for Alzheimer's Disease," <u>Gerontology</u> , 43:79-94 (1997).  |  |
| 315 | SINHA, et al., "Recent advances in the understanding of the processing of APP to beta amyloid peptide," <u>Ann N Y Acad Sci.</u> , 920:206-8 (2000).   |  |
| 368 | SIPE, "Amyloidosis," <u>Annu. Rev. Biochem.</u> , 61:947-975 (1992).   |  |
| 337 | SKOLNICK and FETROW, "From genes to protein structure and function: novel applications of computational approaches in the genomic era," <u>Trends in Biotech</u> , 18(1):34-39 (2000).   |  |
| 319 | SMALL, et al. Alzheimer's disease and Abeta toxicity: from top to bottom. <u>Nat Rev Neurosci</u> . 2(8):595-8 (2001).   |  |
| 427 | SMITH et al., "The challenges of genome sequence annotation or 'The devil is in the details,'" <u>Nature Biotechnology</u> , 15:1222-1223 (1997).  |  |
| 158 | SMITS et al., "Prion Protein and Scrapie Susceptibility," <u>Vet. Quart.</u> , 19(3): 101-105 (1997).  |  |
| 185 | SOLOMON and et al., "Modulation of The Catalytic Pathway of Carboxypeptidase A by Conjugation with Polyvinyl Alcohols," <u>Adv. Mol. Cell Biology</u> , 15A:33-45 (1996).  |  |
| 186 | SOLOMON et al., "Activity of monoclonal antibodies in prevention of in vitro aggregation of their antigens," abstract from Department of Molecular Microbiology and Biotechnology, Tel Aviv University, Tel Aviv, Israel (publication date unknown). |  |
| 159 | SOLOMON et al., "Disaggregation of Alzheimer $\beta$ -amyloid by site-directed mAb," <u>PNAS USA</u> , 94:4109-4112 (1997).  |  |
| 160 | SOLOMON et al., "Monoclonal antibodies inhibit in vitro fibrillar aggregation of the Alzheimer $\beta$ -amyloid peptide," <u>PNAS USA</u> , 93:452-455 (1996).   |  |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
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|       |    |    |    | Examiner Name          |                 |
|       |    |    |    | Attorney Docket Number | 15270J-004727US |

|     |  |  |
|-----|--|--|
| 161 | SOLOMON, A., "Pro-Rx (Protein Therapeutics)," University of Tennessee Medical Center (publication date unknown).   |  |
| 162 | SOLOMON, B., "New Approach Towards Fast Induction of Anti $\beta$ -Amyloid Peptide Immune Response," Department of Molecular Microbiology & Biotechnology, Tel-Aviv University, Ramat Aviv, Tel-Aviv, Israel (publication date unknown).   |  |
| 411 | SOLOMON et al., "The Amino Terminus of the $\beta$ -Amyloid Peptide Contains an Essential Epitope for Maintaining Its Solubility," from <i>Progress in Alzheimer's and Parkinson's Diseases</i> , edited by Fisher et al., Plenum Press, New York, pages 205-211 (1995).               |  |
| 316 | SOTO, et al. Beta sheet breaker peptides inhibit fibrillogenesis in a rat brain model of amyloidosis: implications for Alzheimer's therapy. <i>Nat Med.</i> 4(7):822-6 (1998).   |  |
| 179 | SOUTHWICK et al., "Assessment of Amyloid $\beta$ protein in Cerebrospinal fluid as an Aid in the Diagnosis of Alzheimer's Disease," <i>J. Neurochemistry</i> , 66:259-265 (1996).  |  |
| 369 | SPOONER et al., "The generation and characterization of potentially therapeutic A $\beta$ antibodies in mice: differences according to strain and immunization protocol," <i>Vaccine</i> , 21:290-297 (2002).  |  |
| 271 | ST. GEORGE-HYSLOP et al., "Antibody clears senile plaques," <i>Nature</i> , 40:116-117 (1999).   |  |
| 338 | STEIN et al., "Lack of Neurodegeneration in Transgenic Mice Overexpressing Mutant Amyloid Precursor Protein is Associated with Increased Levels of Transthyretin and Activation of Cell Survival Pathways," <i>The Journal of Neuroscience</i> , 22(17):7380-7388 (September 1, 2002). |  |
| 435 | STERN et al., "Antibodies to the $\beta$ -amyloid peptide cross-react with conformational epitopes in human fibrinogen subunits from peripheral blood," <i>FEBS Letters</i> , 264(1):43-47 (1990).   |  |
| 163 | STOUTE et al., "A Preliminary Evaluation of a Recombinant Circumsporozoite Protein Vaccine Against <i>Plasmodium Falciparum</i> Malaria", <i>N. Engl. J. Med.</i> , 336(2): 86-91 (1997).  |  |
| 164 | STURCHLER-PIERRAT et al., "Two amyloid precursor protein transgenic mouse models with Alzheimer disease-like pathology," <i>PNAS</i> , 94: 13287-13292 (1997).   |  |
| 361 | SU et al., "Intravascular infusions of soluble $\beta$ -amyloid compromise the blood-brain barrier, activate CNS Glial cells and induce peripheral hemorrhage," <i>Brain Research</i> , 818:105-107 (1999).  |  |
| 272 | SZENDREI, et al., "The effects of aspartic acid-bond isomerization on in vitro properties of the amyloid $\beta$ -peptide as modeled with N-terminal decapeptide fragments," <i>Int. J. Peptide Protein Res.</i> , 47:289-296 (1996).  |  |
| 392 | TAL et al., "Complete Freund's Adjuvant Immunization Prolongs Survival in Experimental Prion Disease in Mice," <i>Journal of Neuroscience Research</i> , 71:286-290 (2003).  |  |

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|   |                        | Examiner Name            |          |
| Sheet 23 of 25  | Attorney Docket Number | 15270J-004727US          |          |

|     |  |  |
|-----|--|--|
| 399 | TAN et al., "Amyloidosis," <u>Histopathology</u> , 25:403-414 (1994).  |  |
| 165 | TANAKA et al., "NC-1900, an active fragment analog of arginine vasopressin, improves learning and memory deficits induced by beta-amyloid protein in rats," <u>European J. Pharmacology</u> , 352:135-142 (1998).  |  |
| 339 | TENNENT et al., "Serum amyloid P component prevents proteolysis of the amyloid fibrils of Alzheimer's disease and systemic amyloidosis," <u>PNAS</u> , 92:4299-4303 (1995).  |  |
| 273 | THORSETT, E.D. et al., "Therapeutic approaches to Alzheimer's disease," <u>Curr. Op. in Chem. Biology</u> , 4:377-382 (2000).  |  |
| 276 | TJERNBERG et al., "Arrest of $\beta$ -amyloid fibril formation by a pentapeptide ligand," <u>Journal of Biological Chemistry</u> , 271:8545-8548 (1996).   |  |
| 166 | TRIEB et al., "Is Alzheimer beta amyloid precursor protein (APP) an autoantigen? Peptides corresponding to parts of the APP sequence stimulate T lymphocytes in normals, but not in patients with Alzheimer's disease," <u>Immunobiology</u> , 191(2-3):114-115 Abstract C.37, (1994). |  |
| 375 | TSUZUKI et al., "Amyloid $\beta$ protein in rat soleus in choroquine-induced myopathy using end-specific antibodies for A $\beta$ 40 and A $\beta$ 42: immunohistochemical evidence for amyloid $\beta$ protein," <u>Neuroscience Letters</u> , 2002:77-80 (1995).                     |  |
| 167 | VAN GOOL et al., "Concentrations of amyloid- $\beta$ protein in cerebrospinal fluid increase with age in patients free from neurodegenerative disease," <u>Neuroscience Letters</u> , 172:122-124 (1994).  |  |
| 317 | VEHMAS, et al. beta-Amyloid peptide vaccination results in marked changes in serum and brain Abeta levels in APPswe/PS1 DeltaE9 mice, as detected by SELDI-TOF-based ProteinChip® technology. <u>DNA Cell Biol.</u> (11):713-21 (2001).  |  |
| 428 | VELAZQUEZ et al., "Aspartate residue 7 in amyloid $\beta$ -protein is critical for classical complement pathway activation: Implications for Alzheimer's disease pathogenesis," <u>Nature Medicine</u> , 3(1):77-79 (1997).  |  |
| 168 | VERBEEK et al., "Accumulation of Intercellular Adhesion Molecule-1 in Senile Plaques in Brain Tissue of patients with Alzheimer's Disease," <u>Amer. Journ. Pathology</u> , 144(1):104-116 (1994).   |  |
| 410 | VERMA et al., "Gene therapy - promises, problems and prospects," <u>Nature</u> , 389:239-242 (1997).   |  |
| 169 | WALKER et al., "Labeling of Cerebral Amyloid <i>In Vivo</i> with a Monoclonal Antibody," <u>J. Neuropath. Exp. Neurology</u> , 53(4):377-383 (1994).   |  |
| 274 | WEINER et al., "Nasal administration of amyloid- $\beta$ peptide decreases cerebral amyloid burden in a mouse model of Alzheimer's disease," <u>Annals of Neurology</u> , 48:567-579 (2000).   |  |

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|   |                        | First Named Inventor     | Schenk   |
|   |                        | Art Unit                 |          |
| Examiner Name   |                        |                          |          |
| Sheet 24 of 25  | Attorney Docket Number | 15270J-004727US          |          |

|  |     |  |  |
|--|-----|--|--|
|  | 171 | WEINER et al., "ORAL TOLERANCE: Immunologic Mechanisms and Treatment of Animal and Human Organ-Specific Autoimmune Diseases by Oral Administration of Autoantigens," <u>Annu. Rev. Immunol.</u> , 12:809-837 (1994).         |  |
|  | 172 | WEISSMANN et al., "Bovine spongiform encephalopathy and early onset variant Creutzfeldt-Jakob disease," <u>Curr. Opin. Neurobiol.</u> , 7: 695-700 (1997).   |  |
|  | 387 | WELDON et al., "Neurotoxicity of A $\beta$ Peptide: Confocal Imaging of Cellular Changes Induced by – Amyloid in Rat CNS <i>In Vivo</i> ," <u>Society for Neuroscience Abstracts</u> , 22(Part 1) (1996). ****               |  |
|  | 429 | WELLS, J. A., "Additivity of Mutational Effects in Proteins," <u>Biochemistry</u> , 29(37):8509-8517 (1990).   |  |
|  | 180 | WEN, G.Y., "Alzheimer's Disease and Risk Factors," <u>J. Food Drug Analysis</u> , 6(2):465-476 (1998).   |  |
|  | 170 | WENGENACK et al., "Targeting Alzheimer amyloid plaques in vivo," <u>Nature Biotech.</u> , 18:868-872 (2000).   |  |
|  | 223 | WISCONSIN ALUMNI RESEARCH FOUNDATION, "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals", U.S. Govt. Res. Develop. Rep., 70(24), 56. (Publication date unknown.) |  |
|  | 385 | WISNIEWSKI et al., "Therapeutics in Alzheimer's and Prion Diseases," <u>Biochemical Society Transactions</u> , 30(4):-574-587 (2002).  |  |
|  | 219 | WONG et al., "Neuritic Plaques and Cerebrovascular Amyloid in Alzheimer Disease are Antigenically Related," <u>PNAS USA</u> , 82:8729-8732 (1985).   |  |
|  | 173 | WOOD et al., "Amyloid precursor protein processing and A $\beta$ 42 deposition in a transgenic mouse model of Alzheimer disease," <u>PNAS USA</u> , 94: 1550-1555 (1997).  |  |
|  | 275 | WU, et al., "Drug targeting of a peptide radiopharmaceutical through the primate blood-brain barrier in vivo with a monoclonal antibody to the human insulin receptor," <u>J. Clin. Invest.</u> , 100:1804-1812 (1997).      |  |
|  | 292 | YAMAGUCHI et al., Diffuse plaques associated with astroglial amyloid $\beta$ protein, possibly showing a disappearing stage of senile plaques," <u>Acta Neuropathol.</u> , 95:217-222 (1998).                                |  |

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|--------------------|--|-----------------|--|

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|     |   |
|-----|---|
| 430 | YANG et al., "Effects of Racemization on the Aggregational Properties of the Amyloid $\beta$ -Peptide in Alzheimer's Disease," abstract # 255 from American Chemical Society 214th National Meeting (1997). |
| 290 | YOUNKIN, "Amyloid $\beta$ vaccination: reduced plaques and improved cognition," <u>Nature Medicine</u> , 7:18-19 (2001).  |

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